

**REMARKS**

Claims 1-20 are pending and were rejected by the Examiner. These rejections are traversed below. Claims 21-36 have been withdrawn from consideration by the Examiner. Claims 37-50 have been added. It is respectfully submitted that these newly added claims are supported by the specification, claims, abstract and drawings as originally filed and that no new matter has been added.

***Claim Rejections under 35 U.S.C. §112, ¶1***

The Examiner rejected claims 1-20 under 35 U.S.C. §112, ¶1, arguing that the specification does not enable "inactive ingredients." The subject section and paragraph relied upon in making this rejection actually consists of two separate requirements: (1) that the specification disclose the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains;" and (2) that the specification disclose the "best mode contemplated by the inventor." While it is not entirely clear as to which requirement the Examiner contends is not met, each are addressed in turn.

As set forth in the attached *Declaration of José Zayas-Rivera, Ph.D.*, "inactive ingredients" are terms that are well known and commonly used by those skilled in the art. Indeed,

they are defined by regulation at 21 C.F.R. 210.3(b)(8), and over 700 such "inactive ingredients" are approved by the FDA. Listing all 700 inactive ingredients approved by that government agency would not comply with the requirement of 35 U.S.C. §112, ¶1, because such a listing would not comply with the requirement that the specification be "concise." "Inactive ingredients" is a term that is well understood and commonly used by those skilled in the art and complies with the requirement that the specification be "concise." Accordingly, the subject claims comply with the first requirement of 35 U.S.C. §112, ¶1.

The second requirement, namely disclosing the best mode, is also met. Specifically, the specification expressly identifies the "inactive ingredients" that are preferred for use in making a gel, a cream, a liquid, etc. There is no requirement that the claims be limited to the best mode, only that it be disclosed in the specification. Accordingly, the subject claims comply with the second requirement of 35 U.S.C. §112, ¶1, and the rejection is respectfully traversed.

***Claim Rejections under 35 U.S.C. §112, ¶2***

The Examiner has also rejected claims 1-20 under 35 U.S.C. §112, ¶2, arguing that the claims are broad and not limited to the specific inactive ingredients identified by the preferred

embodiments. It is respectfully submitted that applicants need not limit the claims only to the best mode or the specific preferred embodiments. While the claims may broadly cover any inactive ingredient, as known and understood by those skilled in the art, such breadth should not be equated with indefiniteness. See MPEP §2173.04 ("Breadth of a claim is not to be equated with indefiniteness.") Accordingly, it is respectfully submitted that the subject claims are broad, not indefinite, and the Examiner's objection is respectfully traversed.

#### ***Newly Added Claims***

Claims 37-50 have been added to further recite applicants' invention. Following the Examiner's suggestions, these claims avoid the use of the terms "inactive ingredients." Accordingly, it is respectfully submitted that these claims stand in condition for allowance.

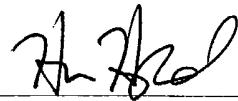
#### ***Conclusion***

For the forgoing reasons, it is respectfully submitted that the application stands in condition for allowance. The Examiner's further consideration and favorable action are respectfully requested.

Respectfully submitted,

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By:



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